

DECISION

no. 26/03.07.2015

on approval of the Romanian version of Standard Terms for pharmaceutical dosage forms for parenteral use, as approved by the European Pharmacopoeia Commission

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 374/02.04.2014, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 03.07.2015, in accordance with Article 12(5) of Government Decision no. 734/2010 on establishment, organization and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following:

DECISION

Sole article - The Romanian version of Standard Terms for pharmaceutical dosage forms for parenteral use, as approved by the European Pharmacopoeia Commission (available in the EDQM database, *revised, the version of 14 November 2014*), is approved, in accordance with the Annex, which is integral part of this Decision.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Acad. Prof. Dr. Leonida Gherasim

<i>No.</i>	<i>Status</i>	<i>English</i>	<i>Romanian</i>
1	Pending	<i>Concentrate for concentrate for solution for inf.</i>	<i>Concentrat pentru concentrat pentru a solution for inf.</i>
2	Current	<i>Concentrate for dispersion for inf.</i>	<i>Concentrat pentru dispersie perfuzabilă</i>
3	Current	<i>Concentrate for emulsion for inf.</i>	<i>Concentrat pentru emulsie perfuzabilă</i>
4	Current	<i>Concentrate for haemodialysis solution</i>	<i>Concentrat pentru soluție pentru hemodializă</i>
5	Current	<i>Concentrate for solution for inf.</i>	<i>Concentrat pentru soluție perfuzabilă</i>
6	Current	<i>Concentrate for solution for inj.</i>	<i>Concentrat pentru soluție injectabilă</i>
7	Current	<i>Concentrate for solution for inj. / inf.</i>	<i>Concentrat pentru soluție injectabilă perfuzabilă</i>
8	Deprecated	<i>Concentrate for suspension for inf.</i>	<i>Concentrat pentru suspensie perfuzabilă</i>
9	Pending	<i>Concentrate for suspension for inj.</i>	<i>Concentrat pentru suspensie injectabilă</i>
10	Pending	<i>Dispersion for concentrate for dispersion for inf.</i>	<i>Dispersie pentru concentrate for dispersion for inf.</i>
11	Current-new	<i>Dispersion for inf.</i>	<i>Dispersie perfuzabila</i>
12	Current	<i>Dispersion for inj.</i>	<i>Dispersie injectabilă</i>
13	Pending	<i>Dispersion for inj./inf.</i>	<i>Dispersie injectabilă / perfuzabila</i>
14	Pending	<i>Emulsion for emulsion for inj.</i>	<i>Emulsie pentru emulsie injectabila</i>
15	Current	<i>Emulsion for inf.</i>	<i>Emulsie perfuzabila</i>
16	Current-new	<i>Emulsion for inj.</i>	<i>Emulsie injectabila</i>
17	Current	<i>Emulsion for inj./inf.</i>	<i>Emulsie injectabilă / perfuzabila</i>
18	Pending	<i>Gas for dispersion for inf.</i>	<i>Gaz pentru dispersie perfuzabila</i>

19	Pending	<i>Gas for dispersion for inj.</i>	<i>Gaz pentru dispersion for inj. / perfuzabila</i>
20	Pending	<i>Gas for dispersion for inj./inf.</i>	<i>Gaz pentru dispersion for inj. / perfuzabila</i>
21	Current	<i>Gel for inj.</i>	<i>Gel injectabil</i>
22	Pending	<i>Granules for suspension for inj.</i>	<i>Granule pentru suspensie injectabila</i>
23	Current	<i>Implant</i>	<i>Implant</i>
24	Currently revised	<i>Implantation chain</i>	<i>Implantation chain</i>
25	Current-new	<i>Implantation matrix</i>	<i>Matrice implantabila</i>
26	Pending	<i>Implantation paste</i>	<i>Pasta implantabila</i>
27	Current-new	<i>Implantation suspension</i>	<i>Suspensie implantabila</i>
28	Current-new	<i>Implantation tablet</i>	<i>Comprimat implantabil</i>
29	Current	<i>Intravesical solution/solution for inj.</i>	<i>Soluție intravezicală/soluție injectabilă</i>
30	Rejected	<i>Kit for implant</i>	<i>Kit pentru implant</i>
31	Currently revised	<i>Living tissue equivalent</i>	<i>Echivalent tisular viu</i>
32	Pending	<i>Matrix for implantation matrix</i>	<i>Matrice pentru matrice implantabila</i>
33	Current-new	<i>Powder for concentrate for dispersion for inf.</i>	<i>Pulbere pentru concentrat pentru dispersie perfuzabilă</i>
34	Deprecated	<i>Powder for concentrate for haemodialysis solution</i>	<i>Pulbere pentru concentrat pentru soluție de hemodializă</i>
35	Current	<i>Powder for concentrate for solution for haemodialysis</i>	<i>Pulbere pentru concentrat pentru soluție pentru hemodializă</i>
36	Current	<i>Powder for concentrate for solution for inf.</i>	<i>Pulbere pentru concentrat pentru soluție perfuzabilă</i>
37	Current	<i>Powder for concentrate for solution for inj./inf.</i>	<i>Pulbere pentru concentrat pentru soluție injectabila / perfuzabilă</i>

38	Current-new	<i>Powder for dispersion for inf.</i>	<i>Pulbere pentru dispersie perfuzabilă</i>
39	Pending	<i>Powder for dispersion for inj.</i>	<i>Pulbere pentru dispersie injectabilă</i>
40	Pending	<i>Powder for emulsion for inj.</i>	<i>Pulbere pentru emulsie injectabilă</i>
41	Pending	<i>Powder for implantation matrix</i>	<i>Pulbere pentru matrice implantabila</i>
42	Pending	<i>Powder for implantation paste</i>	<i>Pulbere pentru pasta implantabila</i>
43	Currently revised	<i>Powder for implantation suspension</i>	<i>Pulbere pentru suspensie implantabila</i>
44	Current-new	<i>Powder for intravesical solution/solution for inj.</i>	<i>Pulbere pentru soluție intravezicala / soluție injectabila</i>
45	Rejected	<i>Powder for nebuliser solution/solution for inj./inf.</i>	<i>Pulbere pentru solutie de inhalat prin nebulizator / solutie injectabila / perfuzabila</i>
46	Current-new	<i>Powder for prolonged-release suspension for inj.</i>	<i>Pulbere pentru suspensie injectabila cu eliberare prelungita</i>
47	Current	<i>Powder for solution for inf.</i>	<i>Pulbere pentru a solution for inf.</i>
48	Current	<i>Powder for solution for inj.</i>	<i>Pulbere pentru soluție injectabila</i>
49	Deprecated	<i>Powder for solution for inj./inf.</i>	<i>Pulbere pentru soluție injectabila sau perfuzabila</i>

50	Current	<i>Powder for solution for inj./inf.</i>	<i>Pulbere pentru soluție injectabilă / perfuzabilă</i>
51	Pending	<i>Powder for solution for inj./skin-prick test</i>	<i>Pulbere pentru soluție injectabilă / test cutanat prin intepare</i>
52	Deprecated	<i>Powder for solution/suspension for inj.</i>	<i>Pulbere pentru soluție / suspensie injectabilă</i>
53	Current	<i>Powder for suspension for inj.</i>	<i>Pulbere pentru suspensie injectabilă</i>
54	Current	<i>Prolonged-release suspension for inj.</i>	<i>Suspensie injectabilă cu eliberare prelungită</i>
55	Current-new	<i>Solution for cardioplegia</i>	<i>Soluție pentru cardioplegie</i>
56	Current	<i>Solution for haemodiafiltration</i>	<i>Soluție pentru hemodiafiltrare</i>
57	Current	<i>Solution for haemodialysis</i>	<i>Soluție pentru hemodializă</i>
58	Current	<i>Solution for haemodialysis/haemofiltration</i>	<i>Soluție pentru hemodializă/hemofiltrare</i>
59	Current-new	<i>Solution for haemofiltration</i>	<i>Soluție pentru hemofiltrare</i>
60	Current	<i>Solution for inf.</i>	<i>Soluție perfuzabilă</i>
61	Deprecated	<i>Solution for inf. and oral solution</i>	<i>Soluție perfuzabilă și soluție orală</i>

62	Current	<i>Solution for inj.</i>	<i>Soluție injectabilă</i>
63	Rejected	<i>Solution for inj./concentrate for solution for inf.</i>	<i>Soluție injectabilă / concentrat pentru a solution for inf.</i>
64	Current	<i>Solution for inj./inf.</i>	<i>Soluție injectabilă / perfuzabila</i>
65	Rejected	<i>Solution for inj./inf./rectal use</i>	<i>Soluție injectabilă / perfuzabilă / administrare rectala</i>
66	Pending	<i>Solution for inj./skin-prick test</i>	<i>Soluție injectabila / test cutanat prin intepare</i>
67	Pending	<i>Solution for solution for inj.</i>	<i>Soluție pentru soluție injectabilă</i>
68	Pending	<i>Solution for suspension for inj.</i>	<i>Soluție pentru suspensie injectabilă</i>
69	Current-updated	<i>Solvent for parenteral use</i>	<i>Solvent pentru preparate parenterale</i>
70	Current	<i>Solvent for solution for inf.</i>	<i>Solvent pentru a solution for inf.</i>
71	Pending	<i>Suspension for emulsion for inj.</i>	<i>Suspensie pentru emulsie injectabila</i>
72	Deprecated	<i>Suspension for inf.</i>	<i>Suspensie perfuzabila</i>
73	Current	<i>Suspension for inj.</i>	<i>Suspensie injectabila</i>
74	Pending	<i>Suspension for suspension for inj.</i>	<i>Suspensie pentru suspensie injectabila</i>

Current = Standard Term (ST) approved for use by the European Pharmacopoeia (PhEur) Commission; the Romanian version has been approved in a previous meeting of the NMA/NAMMD Scientific Council

Current – new = Standard Term approved for use by the European Pharmacopoeia Commission, the Romanian version has been approved in the session of the NAMMD Scientific Council of 03.07.2015.

Deprecated = The Standard Term is not approved for use by the European Pharmacopoeia Commission; It is not physically rejected from the database; kept in order to ensure the term's traceability standard.

Rejected = The Standard Term has been **rejected** during assessment within the *Standard Terms Working Party of the EDQM* and is not approved for use as a Standard Term; Included in the database in order to avoid transmission of new requests to the PhEur Commission for this term

Pending = the proposed term **undergoes assessment** by the *Standard Terms Working Party of the EDQM*.

Draft = the definition undergoes assessment within the **Standard Terms Working Party of the EDQM**.

Currently revised = Standard Term approved for use by the European Pharmacopoeia Commission; a new version of the translation into Romanian of the respective Standard Term has been approved