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| Prepared by: | ACTIVE PHARMACEUTICAL INGREDIENT | Revision: A/2007 |
| Approved by: | | Valid from: 11.06.2007 |

Chemical Name : potassium hydrogen dl-aspartate semihydrate

Chemical Formula : $C_4H_6NO_4K \cdot 0.5 H_2O$

Molecular Weight : 180.2

Storage Conditions : 5 ÷ 30°C; 50 ÷ 80 RH%; indoor

CAS No. : 923-09-1

**DMF SPECIFICATION A
(complies with DAB10)**

| PROPERTY | REQUIREMENT | TEST METHOD |
|---|--|---------------------------|
| Appearance | white crystalline powder or colourless crystals | visual examination |
| Identification | A, C, D and E | DAB10 |
| Water solution 2.5 g/100ml | clear and colourless | DAB10 |
| pH value (2.5% solution) | from 6.0 to 8.0 | DAB10 |
| Related substances | compliance test | DAB10 |
| Chlorides | n.m.t. 200 ppm | DAB10 |
| Sulfates | n.m.t. 300 ppm | DAB10 |
| Ammonium | n.m.t. 200 ppm | DAB10 |
| Iron | n.m.t. 30 ppm | DAB10 |
| Heavy metals | n.m.t. 10 ppm | DAB10 |
| Water (KF) | from 3.0 to 7.0 %(w/w) | DAB10 |
| Assay | from 98.0 to 102.0 %(w/w) | DAB10 |
| n.m.t. – not more than | | |
| STANDARD PACKAGING : fibre drums for 25 kg or 50 kg of product : cardboard boxes for 25 kg of product | | |
| STABILITY : 48 months | | |
| Document Ref. No. : ZN-98/NOV-2 | | Number of Pages: 1 |